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(4818CIP1)

CLAIM AMENDMENTS

1. (Currently Amended) A system for repairing a cardiac valve, comprising:

a flexible guide shaft for extending from a site outside a patient through a vascular lumen to an area about the cardiac valve;

a flexible inner shaft supporting at its distal end a remotely controlled tool for performing a cardiac repair procedure, the inner shaft received in and removably threaded through the guide shaft for disposing said tool at the area about the cardiac valve;

a user interface having an input device operated by a user for control of at least one of said shafts; and

a retainer adapted to being attached to an annulus of the cardiac valve, and being closeable via the tool to draw the annulus into a smaller diameter.

2. (Previously Presented) The system of claim 1, wherein the retainer comprises a ring of predetermined diameter attachable to the annulus.

3. (Original) The system of claim 1, wherein the retainer comprises a ring and any one or a combination of wire clips and sutures.

4. (Currently Amended) The system of claim 1, wherein the ring comprises nitinol ~~Nitinol~~.

5. (Original) The system of claim 1, wherein the retainer comprises a fiber disposed peripherally about a ring, the fiber constructed and arranged for penetration through tissue.

6. (Original) The system of claim 5, wherein the fiber comprises a securing piece disposed about at least one end of the fiber.

7. (Original) The system of claim 5, wherein the securing piece comprises an associated retaining button capable of sliding along the fiber.

8. (Original) The system of claim 5, wherein the tool is adapted to engage the securing piece.

9. (Original) The system of claim 5, wherein the tool comprises a set of jaws.

10. (Original) The system of claim 5, the retainer further including means to tighten the fiber.

11. (Original) The system of claim 1, wherein the flexible inner shaft comprises a controlled flexible segment, for controllably bending the inner shaft at the flexible segment, thereby controlling a position of the tool.

12. (Currently Amended) A system for remotely repairing a cardiac valve, comprising:

a guide catheter for extending intraluminally through a vascular vessel of the human body, so that a distal end of the guide catheter ~~being~~ is disposed at an area about the cardiac valve;

a fiber for extending about a diameter of an annulus of the cardiac valve, so that the fiber ~~being engaged~~ engages with the diameter of the annulus and ~~capable of drawing~~ draws the annulus into a smaller diameter; and

a flexible working catheter received by and threaded through the guide catheter, the working catheter including a tool engageable with the fiber; and a remote manipulator controlled by a user from a site remote from the body, for controlling the tool.

13. (Original) The system of claim 12, wherein the tool comprises a pair of jaws for grasping the fiber.

14. (Original) The system of claim 12, further comprising a monitor for determining a reduction or elimination in valve regurgitation.

15. (Original) The system of claim 14, wherein the monitor comprises an ultrasound monitor.

16. (Original) The system of claim 12, wherein the flexible working catheter comprises a controlled flexible segment, for controllably bending the inner shaft at the flexible segment, thereby controlling a position of the tool.

17. (Previously Presented) A method of repairing a mitral valve of the heart, comprising:

extending a guide shaft through a vascular vessel from a site outside the patient to a site adjacent the mitral valve;

inserting a fiber through the guide shaft;

securing the fiber about an annulus of the mitral valve while the heart is beating, the securing step including introducing through the guide shaft a flexible inner shaft having a remotely controlled distal tool for securing the fiber about the annulus leaving opposite ends of the fiber exposed; and

applying a force to the fiber ends so as to draw the annulus into a tighter diameter.

18. (Original) The method of claim 17, wherein the securing step further comprises securing an end piece of the fiber at a trigone area of the mitral valve.

19. (Original) The method of claim 18, including providing a second securing piece to another end of the fiber so as to draw the fiber tautly so as to draw the annulus into a tighter diameter so as to reduce or eliminate valve regurgitation.

20. (Previously Presented) The method of claim 17, wherein the flexible inner shaft is capable of controlled bending via a remote manipulator.

21. (Original) The method of claim 17, wherein the step of extending the guide shaft comprises passing the guide shaft through an inferior vena cava to the right atrium.

22. (Original) The method of claim 17, wherein the step of extending the guide shaft comprises passing the guide shaft from above the jugular vein or from below the femoral vein.

23. (Original) The method of claim 17, wherein the step of extending the guide shaft comprises puncturing an incision in a wall of the right atrium, and passing the guide shaft through the incision into the left atrium.

24. (Original) The method of claim 17, wherein the step of extending the guide shaft comprises securing the guide shaft to a septal wall between the left atrium and the right atrium.

25. (Original) The method of claim 24, wherein the guide shaft is maintained at a desired position at the septal wall via a balloon.

26. (Original) The method of claim 25, further comprising inflating the balloon in the left atrium to maintain a desired position of a distal end of the guide shaft.

27. (Currently Amended) A method of repairing a mitral valve of the heart, comprising:

extending a guide shaft from a site outside the patient through a vascular lumen to a site about the mitral valve;

providing a ring of a first diameter, the ring being deformable and capable of matching a desired predetermined diameter of an annulus of the mitral valve, the ring engaged with the guide shaft via a flexible inner shaft received by and threaded through the guide shaft; and

securing the ring about the mitral valve annulus while the heart is beating, the securing step including engaging the ring about a circumference of the annulus via a remotely controlled tool supported at a distal end of the inner shaft, and drawing the annulus into the predetermined diameter.

28. (Original) The method of claim 27, wherein the securing includes attaching one side of the ring to the annulus by at least one wire clip.

29. (Original) The method of claim 28, wherein the ring is secured by the wire clip at the trigone area of the mitral valve.

30. (Original) The method of claim 28, wherein the ring is secured by sutures.

31. (Original) The method of claim 30, wherein the sutures are drawn by the flexible inner shaft to draw the annulus into the predetermined diameter.

32. (Original) The method of claim 27, wherein the flexible inner shaft is remotely controlled for a bending at a predetermined segment.

33. (Original) The method of claim 27, wherein the step of extending the guide shaft comprises puncturing an incision in a wall of the right atrium, and passing the guide shaft through the incision into the left atrium.

34. (Original) The method of claim 27, wherein the step of extending the guide shaft comprises securing the guide shaft through a septa1 wall between the left atrium and the right atrium.

35. (Original) The method of claim 34, wherein the guide shaft is maintained at a desired position at the septa1 wall via a balloon.

36. (Original) The method of claim 35, further comprising inflating the balloon in the left atrium to secure a distal end of the guide shaft.

37. (Original) A method of repairing a cardiac valve, comprising:

providing a balloon supported on a catheter member;

supporting a plurality of peripherally disposed anchor pins from an outer surface of the balloon, the anchor pins being tethered together;

passing the balloon in a deflated state to an area about the cardiac valve;

inflating the balloon to thrust the anchor pins into an annulus of the cardiac valve; and

tightening the tether to pull the peripherally disposed pins into a smaller diameter.

38. (Original) The method of claim 37, wherein the balloon in its deflated state passes through the left ventricle of the heart into the area about the cardiac valve.

39. (Original) The method of claim 37, wherein the cardiac valve is the mitral valve.

40. (Original) The method of claim 37, wherein the providing comprises providing a balloon of predetermined length having the anchor pins disposed at approximately a center section thereof.

41. (Original) A method for repairing a cardiac valve, comprising:

providing a balloon;

supporting and passing the balloon in a deflated state to an area about the cardiac valve;

disposing a plurality of peripherally disposed anchor pins arranged about an outer surface of the balloon, and a tether for intercoupling said anchor pins;

inflating the balloon once positioned at the area about the cardiac valve to thrust the anchor pins into a ring defining a base of the cardiac valve; and

tightening the tether to pull the peripherally disposed pins into a smaller diameter.

42. (Currently Amended) A system for remotely repairing a cardiac valve, comprising:

a flexible guide shaft <u>for</u> extending through an area of the human body so as to locate a distal end thereof at an area about the cardiac valve;

a delivery member for supporting an array of securing pieces at a distal end thereof and extending through said flexible guide member, the array of securing pieces being intercoupled by a cable; <u>and</u>

a remote manipulator <u>for being</u> controlled from a site remote from the body, for controlling the delivery member to expel the securing pieces in sequence about the cardiac

valve annulus as the valve is functioning, the remote manipulator capable of controlling a tightening of the cable to draw the annulus into a smaller diameter.

43. (Original) The system of claim 42, wherein the remote manipulator comprises a manually controlled input device, and a computer processing unit for interpreting manipulations of the input device.

44. (Original) The system of claim 42, wherein the securing pieces comprise metal anchor pieces, each having a closed loop for receiving the cable.

45. (Original) The system of claim 44, wherein the delivery member includes an inner flexible shaft, and the anchor pieces have end legs constructed of a material deformable to fit within the inner flexible shaft.

46. (Original) The system of claim 45, wherein the end legs, once deployed, are capable of engaging the cardiac valve annulus.

47. (Original) The system of claim 44, wherein the anchor pieces are constructed of an elastic material.

48. (Original) The system of claim 47, wherein the elastic material comprises Nitinol.

49. (Original) The system of claim 42, further including a crimp element secured to the cable, that once tightened, is capable of maintaining the annulus in a closed position.

50. (Original) The system of claim 49, further including a crimping tool received by the guide shaft for securing the crimping element, and a cutting tool, later received by the guide shaft for cutting the cable.

51. (Original) The system of claim 42, wherein the array of securing pieces comprises a plurality of staples, and the delivery member comprises a storage housing for the staples.

52. (Original) The system of claim 51, wherein each staple has pointed ends and a center loop for receiving the cable.

53. (Original) The system of claim 51, including a clamping mechanism at a distal end of the storage housing for selectively closing each staple as they progress out of the storage housing.

54. (Original) The system of claim 51, wherein first and last staples are secured at a trigone area of the annulus, and the cable extends outside of the patient for external control of the cable.

55. (Original) The system of claim 51, wherein the release of each staple is controllable by a remotely operated user interface of the remote manipulator.

56. (Original) The system of claim 42, wherein the array of securing pieces comprise staples, each staple being constructed of a deformable material having a closed rest position, and the delivery system includes a holder for retaining the staples in a biased open position in readiness for release.

57. (Original) The system of claim 56, wherein the holder comprises a rod, and the staples are constructed of Nitinol.

58. (Original) The system of claim 42, wherein the delivery member includes an inner flexible shaft member received in the flexible guide shaft, the remote manipulator

capable of controlling multiple degrees-of-freedom of both the flexible guide member and the inner flexible shaft member in the area about the cardiac valve.

59. (Previously Presented) A flexible instrument system for repairing an anatomic body part, comprising:

an instrument shaft having sufficient flexibility along a length thereof so as to readily flex and conform to a vascular lumen pathway in the anatomy as the shaft is inserted therein;

a drivable mechanism disposed at a proximal end of the instrument shaft for controlling a tool supported at a distal end of the instrument shaft,

the instrument shaft being insertable into a subject threaded through a flexible guide shaft so as to dispose the distal end of the instrument shaft at an internal site of an anatomic body part; and

a retainer, adapted to being attached to an annulus at the anatomic body part, the retainer being closeable so as to draw the annulus into a smaller diameter.

60. (Previously Presented) The system of claim 59, wherein the instrument shaft and drivable mechanism are disposable as a unit.

61. (Original) The system of claim 59, further comprising a remote drive unit for controlling the drivable mechanism.

62. (Previously Presented) The system of claim 61, wherein the instrument shaft is detachable from the drive unit and is portable.

63. (Previously Presented) The system of claim 59, wherein the instrument shaft is remotely controlled from a user interface in performing the repair.

64. (Original) The system of claim 59, wherein the retainer comprises a fiber, wire, or a cable sewn to the annulus via the tool.

65. (Previously Presented) The system of claim 59, wherein the retainer comprises a ring having a predetermined diameter matching that of the desired diameter of the annulus, the ring being deformable for receiving by the instrument shaft.

66. (Original) The system of claim 59, wherein the retainer comprises an array of anchor pieces.

67. (Original) The system of claim 59, wherein the retainer comprises a plurality of staples.

68. (Original) The system of claim 67, wherein the staples are constructed of a deformable material.

69. (Currently Amended) The system of claim 68, wherein the staples are constructed of ~~nitinol~~ Nitinol.

70. (Original) The system of claim 59, wherein the retainer is closeable by a crimp element.

71. (Previously Presented) The system of claim 59, wherein both shafts are remotely controllable with multiple degrees-of-freedom.

72. (Previously Presented) The system of claim 1 wherein the flexible guide shaft includes a controlled flexible segment for controllably bending the guide shaft, thereby controlling a positioning of the tool.

73. (Previously Presented) The system of claim 72, wherein the flexible segment is controllable by the user from the user interface.

74. (Previously Presented) The system of claim 1 further including a drive unit for the system and an electrical controller responsive to the user interface for controlling the drive unit.

75. (Previously Presented) The system of claim 12, wherein the guide catheter includes a controlled flexible segment for controllably bending the guide catheter, thereby controlling a positioning of the tool.

76. (Previously Presented) The system of claim 75, wherein the flexible segment is controllable by the user from the user interface.

77. (Previously Presented) The system of claim 12 further including a drive unit for the system and an electrical controller responsive to the user interface for controlling the drive unit.

78. (Previously Presented) The method of claim 17 including remotely controlling the guide shaft.

79. (Previously Presented) The method of claim 78 including providing a controllable flexible segment of the guide shaft for controllably bending the guide shaft, thereby controlling a positioning of the tool.

80. (Previously Presented) The method of claim 27 wherein the flexible inner shaft is remotely controlled from a user interface with a manually operated input device.

81. (Previously Presented) The method of claim 27 including remotely controlling the guide shaft.

82. (Previously Presented) The method of claim 8 1 including providing a controllable flexible segment of the guide shaft for controllably bending the guide shaft, thereby controlling a positioning of the tool.

83. (Previously Presented) The system of claim 59 wherein the flexible guide shaft includes a controlled flexible segment for controllably bending the guide shaft, thereby controlling a positioning of the tool.

84. (Previously Presented) The system of claim 59 wherein both shafts include a remotely controllable bendable section, controlled from a user at a user interface via an electrical controller.

85. (Currently Amended) A flexible instrument system for performing a medical procedure on an anatomic part at an internal operative site, said instrument system comprising:

a flexible guide shaft extending from a site outside a patient through an anatomic vascular lumen to the area of the operative site;

an inner flexible instrument shaft supporting at its distal end a tool that is controllable in assisting in the medical procedure on the anatomic part, said inner flexible instrument shaft received in and removably threaded through the guide shaft for disposing said tool at said operative site;

a user interface at which a medical practitioner manipulates an input device;

<u>a drive unit for at least one of the shafts;</u> and

an electrical controller coupled between the user interface and ~~a~~ the drive unit for at least one of the shafts, and that receives a command from said input device for controlling positioning of said at least one of said shafts so as to respond in accordance with action at the input device in performing the medical procedure.

86. (Previously Presented) The system of claim 85 wherein at least one of said shafts includes a remote controllable flexible segment for controlling the disposition of the tool.

87. (Previously Presented) The system of claim 86 wherein the guide shaft is remotely controlled from the user interface.

88. (Previously Presented) The system of claim 86 wherein the instrument shaft is remotely controlled from the user interface.

89. (Previously Presented) The system of claim 85 wherein the tool is used in performing a cardiac repair procedure.

90. (Currently Amended) The system of claim 85 ~~including a~~ wherein the drive unit is for ~~at least one~~ both of said shafts.

91. (Currently Amended) A method for performing a medical procedure on an anatomic part at an internal operative site, ~~said instrument system~~ comprising:

extending a flexible guide shaft from a site outside a patient through an anatomic vascular lumen to the area of the operative site;

threading an inner flexible instrument shaft, that supports at its distal end a tool that is controllable in assisting in the medical procedure, through the guide shaft for disposing said tool at said operative site;

manipulating a user interface at which a medical practitioner manipulates an input device; and

providing a controller coupled between the user interface and a drive for at least one of the shafts, and that receives a command from said input device for controlling positioning of at least one of said shafts so as to respond in accordance with action at the input device in performing the medical procedure.

92. (Previously Presented) The method of claim 91 wherein the step of extending the flexible guide shaft comprises passing the flexible guide shaft through an inferior vena cava to the right atrium.

93. (Previously Presented) The method of claim 91, wherein the step of extending the flexible guide shaft comprises passing the flexible guide shaft from above via the jugular vein or from below via the femoral vein.

94. (Previously Presented) The method of claim 91, wherein the step of extending the flexible guide shaft comprises puncturing an incision in a wall of the right atrium, and passing the flexible guide shaft through the incision into the left atrium.

95. (Previously Presented) A flexible instrument system for performing a medical procedure at a target site of the heart, said system comprising:

a flexible instrument shaft having proximal and distal ends with at least one flexible segment extending through a vascular lumen of the human body;

a flexible guide tube extending through the vascular lumen;

the flexible instrument shaft being threaded through the guide tube, the flexible instrument shaft and guide tube adapted to conform to the configuration of the lumen;

said flexible instrument distal end being a working end for assisting in performing the medical procedure on the heart;

a user interface at which a medical practitioner manipulates an input device;

an electrical controller that receives a command from said input device and for controlling the position of the flexible guide tube so as to respond in accordance with action at the input device in performing the medical procedure; and

means for detecting an anatomically sensed signal and displaying the content thereof.

96. (Previously Presented) The system of claim 95 wherein the means for detecting comprises an electro-potential sensor for sensing electrophysiological signals.

97. (Previously Presented) The system of claim 96 further including a drive unit, a mechanically drivable mechanism at the proximal end of the flexible instrument shaft and drivably coupled to a tool, and a mounting mechanism drivably intercoupled with the drive unit, the mechanically drivable mechanism being removably mountable on the mounting mechanism for drivable intercoupling with the drive unit.

98. (Previously Presented) The system of claim 95 including a tool at the working end of the flexible instrument shaft.

99. (Previously Presented) The system of claim 96 wherein the electrophysiological signals are used to aid in locating the position of the tool.

100. (Previously Presented) The system of claim 96 wherein the electro-potential sensor is the flexible instrument shaft.

101. (Previously Presented) The system of claim 95 wherein said flexible guide tube has a remote controlled bendable section that is telerobotically controlled for bending from said input device.

102. (Previously Presented) The system of claim 95 wherein the means for detecting comprises at least one of force, position, vibration, acoustics, auditory, visual, neurological stimulus, electro-potential and biochemical sensing.